

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE

25-05

5/4/05

USE OF MICROBIAL PATHOGEN COMPUTER MODELING IN HACCP PLANS

I. What is the purpose of this Notice?

This provides inspection program personnel with information about Microbial Pathogen Computer Modeling (MPCM) programs and appropriate verification activities when an establishment uses MPCM programs in validating and maintaining its HACCP plans. FSIS has also developed guidance material about MPCM programs for establishments and inspection program personnel (Attachment 1). This information is available on www.usda.fsis.gov.

NOTE: This notice is a reissuance of FSIS Notice 50-04.

II. What is an MPCM program?

An MPCM program is computer-based software that, based on such factors as growth, lethality, and survival in culture broth and food products, estimates the growth or decline of foodborne microbes in food samples in production.

III. How can the MPCM programs be used?

MPCM programs can be valuable tools for establishments to use in supporting hazard analyses, developing critical limits, and evaluating the relative severity of problems caused by process deviations. They can also be used to help predict the expected effectiveness of corrective actions.

IV. What are the limitations of MPCM programs?

It is not possible or appropriate to rely solely upon a predictive modeling program to determine the safety of foods and processing systems. Determining pathogen growth or survival and controlling it in food products requires complete and thorough analysis by an independent microbiology laboratory, challenge studies, and surveys of the literature. The limitations are discussed further in the attached guidance material. MPCM programs do not replace these types of activities or the judgment of a trained and experienced microbiologist.

DISTRIBUTION: Inspection Offices;
T/A Inspectors; Plant Mgt; T/A Plant
Mgt; ABB; TSC; Import Offices

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V. How should inspection program personnel verify the use of MPCM programs?

A. Establishments are responsible for validating their HACCP plans and must justify the use of the conclusions reached by the use of MPCM programs. Inspection program personnel should verify that establishments document the use of MPCM programs as specified in 9 CFR 417.5. Generally, an MPCM program would not be the only documentation relied upon to support an element of a HACCP plan. However, in certain circumstances, a microbiologist or other trained process authority professional may determine the MPCM program is the most appropriate source of data to support HACCP decision making. For example, the control of *Clostridium botulinum* in low acid canning technology has long been established and documented in scientific and other technical reference literature. Provided that the control parameters for *C. botulinum* are incorporated into an MPCM program and accurately reflect the process under review, then the MPCM program may be relied upon as the sole source for decision making for a HACCP element. In such cases, the microbiologist or other trained professional on the HACCP Team must document their decision to use the MPCM as part of the HACCP records.

B. Inspection program personnel should verify that the parameters used in the predictive model match the ones used by the establishment in its process, and that the data produced by the MPCM program were taken into account by the establishment in its decision making process during the HACCP plan development or implementation.

(NOTE: Inspection program personnel should not use or place on Agency computers an establishment's MPCM program. In the future, inspection program personnel may have access to an Agency issued MPCM program.)

C. If inspection program personnel have questions regarding an establishment's use of an MPCM program, they should contact the Technical Service Center. If necessary, a Enforcement Investigation Analyst Officer may respond to the concerns about the establishment's use of the MPCM programs.

Philip S. Derfler /s/

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GUIDELINES FOR THE USE OF MICROBIAL PATHOGEN COMPUTER MODELING IN HAZARD ANALYSIS AND HACCP PLANS

Introduction

Microbial Pathogen Computer Modeling (MPCM) programs are innovative tools based on predictive microbiology. These modeling programs are used for predicting bacterial growth, decline, or inactivation, and survival in culture broth or food substrates. Questions from program and industry personnel have indicated confusion as to whether MPCM programs can be used as part of the validation of a HACCP plan under 9 CFR 417.2 (a) and 417.4 (a) (1).

What Is an MPCM Program?

MPCM programs are computer-based software programs to estimate microbial growth, lethality, or survival in culture broth or food products. These programs can also approximate the growth or decline of foodborne microbes under specific conditions of an experimental protocol. Predictions are based on a bacterial species and its response in broth culture or actual food substrates, to environmental agents, including such intrinsic product characterizations as pH, salt, phosphates, nitrites, and water activity, and such extrinsic influences to the product as temperature and culture atmosphere (such as aerobic or anaerobic). The programs can quantify the effects of two or more such agents on the pathogen and, in some cases, allow extrapolations to be made outside the model's data range.

The Role of MPCM Programs

MPCM programs can be valuable tools for establishments to use in supporting Hazard Analyses, estimating Critical Control Point (CCP) limits and ranges, and evaluating the relative severity of problems caused by process deviations. They are initial estimators of microbial behavior and may be useful as a tool for evaluating potential problems.

A food manufacturing company may use an MPCM program to estimate the influence of each limiting agent or combination of agents during processing. MPCM programs should not be used by themselves though, in lieu of necessary laboratory work and literature searches. They do not necessarily reduce the need for challenge tests, storage trials, and other conventional techniques to assess pathogen growth, decline, or survival. MPCM programs can be used as a measure in evaluating the significance of a specific process deviation.

These programs are useful tools for:

1. Predicting bacterial growth potential or decline in a particular food after specific time-temperatures are reached under specified conditions.
2. Identifying potential CCPs where the model indicates that at a certain level controllable factors will either permit or suppress microbial growth. Allowable limits can be partially based on quantitative predictions of bacterial behavior at different levels under varying conditions.
3. Reformulating product based, at least in part, on conditions that influence microbial growth.
4. Determining product disposition as a consequence of a process deviation; providing information that can be used in decision making; modeling information along with other considerations that may result in a decision to rework, utilize, or condemn product.
5. Providing graphical modeling tools that can be used as instructional aids for demonstrating to employees the impact of following HACCP requirements, maintaining and monitoring equipment, or the benefits of high-quality raw material with initial low microbial populations versus those raw materials with higher populations.

The Limitations of MPCM Programs

It is not yet possible to rely solely upon any predictive modeling program to determine the safety of all foods and processing systems. Determining pathogen growth or survival in food products requires a complete and thorough validation from an independent microbial laboratory, challenge studies, and a survey of the literature. MPCM programs do not replace microbial validation, experimental challenge studies, or the judgment of a trained and experienced microbiologist.

Current MPCM models do not usually include all influences on bacterial growth and survival. Such excluded influences include bacteriocins or anion effects from acidulents, phosphates, sorbates, and humectants other than sodium chloride. Programs do not typically consider the protective buffering effects of various food components when converting predictions from experimental broth cultures to different and more solid food matrices. The programs do not include the inhibitory or supporting effect that the native bacterial population may have on pathogenic bacteria. These effects will vary in different seasons, locales, climates, and other unforeseen events in an establishment. These models do not usually account for increased resistance of bacteria to certain treatments because of prior conditioning of cells, e.g., from heat shock or induced acid tolerance.

The programs are based on a few specific pathogens and the behavior of these pathogens under controlled laboratory conditions. Many of the current models do not consider enrichment growth or competitions among different organisms typically present in foods. Most models do not consider what phase of growth or the physiological state that the modeled bacteria were in when exposed to each of the limiting environmental factors. Because the initial predictive phase of growth of the bacterial cell can be different from the actual conditions, additional laboratory testing may still be needed.

Risk assessments developed in establishments cannot be based on MPCM programs alone. In order to estimate risk, a useful model should be based on complete exposure assessments, dose-response assessments, and risk characterizations to predict the overall risk with attendant uncertainties. Extension of the predictive models to account for the full structure of a risk assessment would require more investment for establishments to develop and use.

Finally, from a statistical point of view, the nature and magnitude of variability and uncertainty associated with predictive models is not completely understood. In some models, the upper and lower confidence intervals may be inaccurate or even missing. In summary, there is no guarantee that predicted values will match those that would occur in any specific food system unless the model was developed for that specific food.

MPCM Programs Used as Part of a Hazard Analysis, the Validation of the HACCP Plan, or a Corrective Action

MPCM programs are support tools that can be used in hazard analyses, identifying critical limits, and validating the HACCP plan. Plant management must realize that MPCM programs are only **predictive tools** for estimating potential growth, lethality, or survival potential for pathogens. As such, predicted values will likely not correspond to those that would occur in any specific food system. These programs can suggest the level of a hazard likely to occur. MPCM programs also help determine whether controllable factors can reduce or eliminate that hazard or correct the process deviation. As a consequence of the uncertainty of the predictive capabilities when applied to a particular set of circumstances, establishments should be extremely careful about how they use these programs, if they choose to use them at all. They should be used in a conservative manner and other factors should play a role in making critical decisions about a process or deviation.

MPCM programs, as stated above, cannot be relied upon as the sole means of ensuring food safety and producing effective process systems for all products. Before the models could be used in such a manner, the user would have to validate the models for each specific food of interest. Initial validation, as defined in 9 CFR 417.4, requires repeated testing of the CCPs and critical limits. Ultimately, predictive models can serve only as a tool for approximating critical limits but not as a replacement for testing for these limits.

MPCM programs can be used as predictive models to ascertain the effects of process deviations or as an analysis tool to assist in determining the relative severity of a deviation. If all factors leading to the deviation can be determined, the MPCM program could be used to show the effects from the deviation and to develop a working plan for corrective action. All other requirements in analyzing the deviation and implementing the corrective action as stated in 9 CFR 417.3 must then be followed.

MPCM Programs and FSIS

FSIS does not approve nor advise industry on the proper use of specific MPCM programs. Industry may wish to contact a process authority or other professional about the use of specific MPCM programs. For particular case use, contact the Technical Service Center.